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Indian Standard

SPECIFICATION FOR AUTOPOLYMERIZING (ACRYLIC) RESINS FOR DENTAL USE

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SPECIFICATION FOR AUTOPOLYMERIZING (ACRYLIC) RESINS FOR DENTAL USE

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0. FOREWORD

0.1 This Indian Standard was adopted by the Indian Standards Institution on 5 May 1978, after the draft finalized by the Dental Materials Sectional Committee had been approved by the Chemical Division Council.

0.2 Autopolymerizing (acrylic) resins for dental use are acrylic polymers in which polymerization is not initiated by heat. These resins are supplied in the form of powder and liquid for the repair of acrylic denture bases. These resins are also known as cold-processing resins.

0.3 In the preparation of this standard, considerable assistance has been derived from AS T 3 I-1970 ' Specification for cold-processing resins for denture repairs ', published by the Standards Association of Australia.

0.4 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS :2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

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1. SCOPE

1.1 This standard prescribes the requirements and the methods of sampling and test for autopolymerizing (acrylic) resin for dental use.

2. REQUIREMENTS

2.1 Description — The material shall be supplied in the form of powder and liquid.

2.1.1 The powder shall consist essentially of polymerized esters of acrylic acid, substituted acrylic acid or interpolymers of these with each other or with vinyl esters.

*Rules for rounding off numerical values (*revised*).

2.1.2 *Liquid* — The liquid shall consist essentially of monomeric material appropriate to the powder. It shall be clear and no substantial colouration shall be produced when it is exposed in a clear glass container to bright diffuse daylight for 24 hours. It shall be free from deposits or sediments and, when maintained at a temperature of 60 ± 2°C for 24 hours in a closed vessel in the dark, it shall not show evidence of thickening.

2.2 The powder and liquid shall effect a satisfactory repair, when used in accordance with the manufacturer's instructions, which shall not produce local tissue reaction or general toxic effects.

2.3 **Hardening** — The resin shall be capable of being ground and polished to a high gloss within 30 minutes from the commencement of mixing, when processed in accordance with the manufacturer's instructions.

2.4 **Colour** — The colour shall be as specified by the purchaser. When coloured, resin shall be translucent and evenly coloured and when clear, resin shall be clear and colourless.

2.5 **Crazing** — When prepared as prescribed in A-2, specimen plates shall show no appreciable evidence of crazing when viewed with naked eye.

2.6 Surface Properties — When prepared as prescribed in A-2, the material shall have a glossy surface.

2.7 **Freedom from Porosity** — When prepared and sectioned as prescribed in A-3, the material shall not show excessive bubbles or voids on visual examination with a magnification of 5 *x* when sectioned.

2.8 **Transverse Properties** — When determined as prescribed in A-4, the transverse deformation of the material shall comply with the requirements given in Table 1.

TABLE 1 TRANSVERSE DEFORMATION

SL No.	Load Increment, kgf	Deformation, mm
(1)	(2)	(3)
i)	1'5 to 2'5	1.5, *Max*
ii)	1.5 to 4·0	1·5 to 4'5

2.9 Water Absorption — When tested as prescribed in A-5, the amount of water absorbed shall not exceed 30 mg.

2.10 Loss in Mass by Leaching — When tested as prescribed in A-5, the amount of material leached shall not exceed 1·6 mg.

2.11 **Colour** Stability — When tested as prescribed in A-6, the material shall not show any change in colour.

3. PACKING AND MARKING

3.1 Packing — The material shall be packed in properly sealed dark brown glass bottles.

3.2 **Marking** — The bottles shall bear legibly and indelibly the following information:

a) Name of the material;

b) Name of the manufacturer and his recognized trade-mark, if any;

c) Net mass/volume of the powder/liquid;

d) Colour (in case of powder only); and

e) Batch number.

3.2.1 *Manufacturer's Instructions* — Adequate and accurate instructions by the manufacturer for storing and using the material shall accompany each container.

3.2.2 The containers may also be marked with the IS1 Certification Mark.

NOTE -The use of the **ISI** Certification Mark is governed by the provisions of the Indian Standards Institution (Certification Marks) Act and the Rules and Regulations made thereunder. The **ISI** Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well-defined system of inspection, testing and quality control which is devised and supervised by **ISI** and operated by the producer. **ISI** marked products are also continuously checked by **ISI** for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the **ISI** Certification Mark may be granted to manufacturers or processors, may be obtained from the Indian Standards Institution.

4. SAMPLING

4.1 Methods of preparation of samples and criteria for conformity shall be as given in Appendix B, or as may be agreed between the purchaser and the supplier.

APPENDIX A
(Clauses 2.5 to 2.11)

METHODS OF TEST FOR AUTOPOLYMERIZING (ACRYLIC) RESINS FOR DENTAL USE

A-l. TEST CONDXTIONS

A-l.1 All tests shall be carried out in a room in which ambient conditions are as follows:

Temperature	27 ± 2°C, and
Relative humidity	55 to 75 percent.

A-2. TEST FOR CRAZING AND SURFACE PROPERTIES

A-2.1 Apparatus -_A denture flask complying with the dimensions shown in Fig. 1, filled with gypsum except for a space in which a tapered rectangular specimen plate of the following dimensions can be processed:

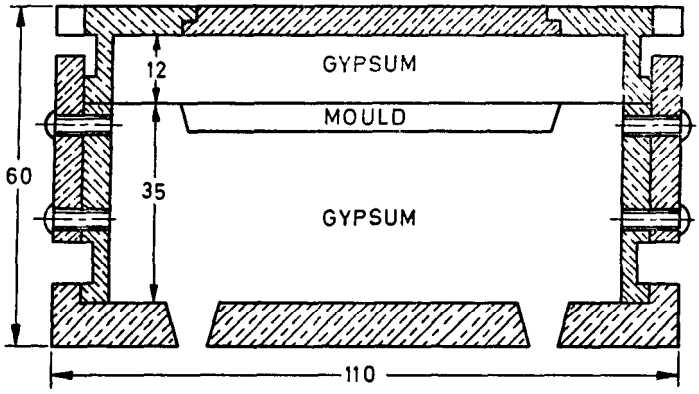
Upper surface	65 x 40 mm
Lower surface	64 x 39 mm
Thickness	5 mm

A-2.2 Procedure

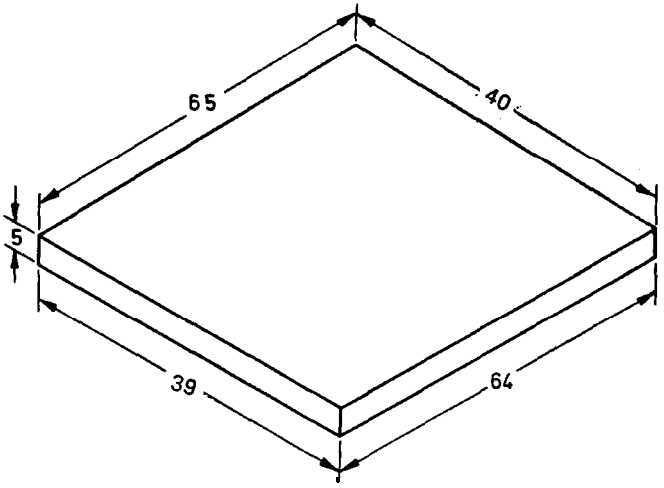
A-2.2.1 Line the space in the denture flask throughout with tin-foil, and prepare clear resin of the hot-processing type, without cross-linking agents, pack into the space provided and process in accordance with the manufacturer's instructions. Prepare two such specimen plates.

A-2.2.2 Saw each plate crosswise in halves and round and polish the sawn edges. Store the halves of each plate in water at a temperature of 37 ± 1°C for not less than 7 days. Then bring to room temperature whilst still immersed. Immediately prior to repairing, wipe the halves of each plate dry and place in their original relative positions in the flask but allowing a gap of 3·0 ± 2 mm between the prepared edges. Join the halves immediately using the repair resin in accordance with the manufacturer's instructions.

A-2.2.3 Upon removal from the flask, examine the specimen plates for compliance with the requirement for crazing properties and the repair material for compliance with the requirement for crazing and surface properties.



DENTURE FLASK



SPECIMEN PLATE

All dimensions in millimetres.

FIG. 1 DENTURE FLASK AND SPECIMEN PLATE

A-3. TEST FOR FREEDOM FROM POROSITY

A-3.1 Saw each repaired specimen (see A-2.2.2) lengthwise into three equal strips. Examine repair material for compliance with the requirement for freedom frorn porosity.

A-3.2 Prepare six repair specimens each measuring 64 (±2) x 10·00 (±0·03) x 2·50 (±0·03) mm from these strips for other tests in the following manner,

A-3.2.1 Mill evenly the strips on both moulded surfaces and the edges so that the dimensions are slightly oversize. Wet ground smooth and flat all faces and edges on waterproof silicon carbide paper to the required dimensions.

A-3.2.2 Store the specimens in water at a temperature of 37 ± 1°C for 7 days.

A-4. DETERMINATION OF TRANSVERSE DEFORMATION

A-4.1 Apparatus

A-4.1.1 ***Testing Machine*** — A machine over the load range of 1'5 kgf to 6 kgf with a constant cross-head movement of 18 ± 3 mm/min and equipped with a device for measuring deflection to within 0·025 mm at the centre of the specimen. The load exerted by the deflection measuring device over its entire operating range shall be accounted for when calibrating the machine load.

A-4.1.2 ***Bending Rig -The*** loading nose and the two supports shall have highly polished cylindrical surfaces 3·2 mm in diameter and parallel to within 0·1 mm over a 10 mm length. The distance between the centres of the supports shall be 50 ± 0·025 mm. The loading nose shall be midway between the support to within 0·025 mm. Means shall be provided to prevent misalignment of the specimen on the supports.

A-4.1.3 ***Water-Bath*** — A bath capable of maintaining the specimen at a temperature of 37·0 ± 1'0°C.

A-4.2 Procedure

A-4.2.1 Subject each of the six specimens prepared in A-3.2 to the following test:

> Place the 10-mm side of the specimen symmetrically on the supports and allow the immersed specimen to come into equilibrium with the water-bath temperature of 37·0 ± 1·0°C. Apply an initial load of 1·5 kgf to the specimen and measure its deflection. It shall then be continuously loaded at 18 ± 3 mm/min to break. Record the deflection to the nearest 0·5 mm at a load of 2·5 kgf and again at a load of 4·0 kgf.

A-4.3 Result — Report the average deflections at the centres of the six specimens tested to the nearest 0·05 mm as the transverse deformation at 2'5 kgf and 4·0 kgf loads respectively.

A-5. DETERMINATION OF WATER ABSORPTION AND LOSS IN MASS BY LEACHING

A-5.1 Preparation of Test Specimens — Prepare the resin and pack into a stainless steel mould of the dimensions shown in Fig. 2 mounted in gypsum in the two halves of a denture Bask. Process according to the manufacturer's instructions. The disc so prepared shall be 50 ± 1 mm diameter and 0·5 ± 0· 1 mm thick. The surface of the disc so prepared shall be smooth and the top and bottom flat.

A-5.2 **Apparatus** — Two desiccators containing silica gel freshly dried at a temperature of 130°C.

A-5.3 **Procedure**

A-5.3.1 Bring one of the desiccators to a temperature within the range of 35 to 39°C and the other to *a* temperature within the range of 20 to 25°C. Prepare a disc of resin (see A-5.1) and place in the desiccator maintained at a temperature within the range 35 to 39°C. Then transfer for one hour to desiccator maintained at a temperature within the range of 20 to 25°C. At the end of this period, weigh to the nearest 0·02 mg. Repeat this cycle until the loss in mass of the disc is not more than 0·4 mg. Record the mass of the disc.

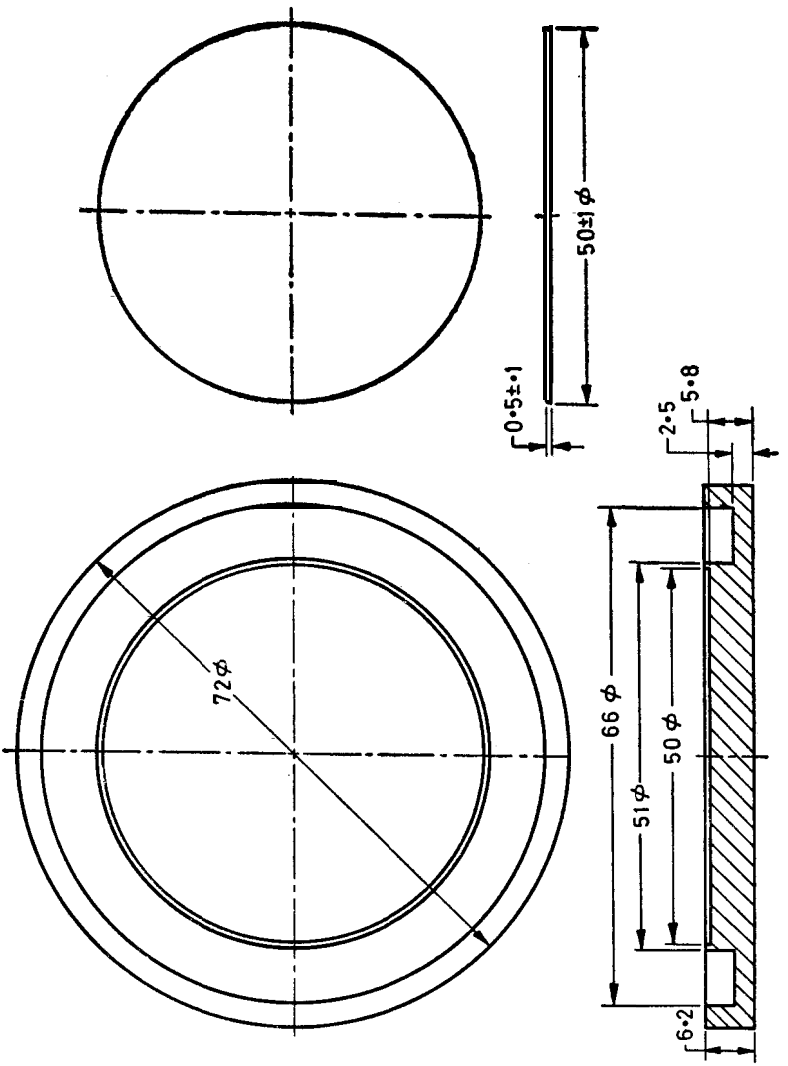
A-5.3.2 Immerse the disc for 24 hours in distilled water maintained at a temperature within the range 35 to 39°C. At the end of this period, remove the disc from the water with tweezers, wipe with a clean dry hand-towel until free from visible moisture, wave in the air for 15 seconds, and determine its mass within 1 minute after removal from water.

A-5.3.3 Place the disc for 24 hours in the desiccator maintained at a temperature within the range of 35 to 39°C. At the end of this period, transfer it to the desiccator maintained at a temperature within the range 20 to 25°C. At the end of this period, weigh to the nearest 0·2 mg. Repeat the drying till the loss in mass of the disc is not more than 0·4 mg. Record the mass of the disc. Test two such specimens. Retain the specimens after the test for use in the determination of colour stability (see A-6).

A-5.4 **Result**

A-5.4.1 *Water Absorption* — Record the difference between the first and second mass and report the average of the two results as the water absorption of the material.

A-5.4.2 Loss in *Mass by Leaching* — Record the difference between the first and the third mass and report the average of the two results as loss in mass by leaching.



All dimensions in millimetres.

FIG. 2 STAINLESS STEEL MOULD AND RESIN SPECIMEN

A-6. DETERMINATION OF COLOUR STABILITY

A-6.1 Apparatus

A-6.1.1 *Lamp* — A lamp fitted with an oxidized aluminium reflector (*see* Fig. 3) 360 mm in diameter at the lower rim and a light source known as an S-l bulb which has been in use for not less than 50 nor more than 400 hours. This light source rated at 400 watts is a combination tungsten-filament mercury-arc enclosed in glass which filters out ultra-violet light below 28 000 nm (2 800 A).

A-6.1.2 ***Turntable*** — A turntable which can be operated at 33 rev/min. The turntable shall support an aluminium disc fitted with a suitable specimen holder such that the distance from the centre of the specimen to the centre of the supporting disc is 12.5 cm.

A-6.2 **Procedure** — Place one of the discs used for the determination of water absorption and loss in mass by leaching (see A-5) in the holder and centre the aluminium disc under the S-l bulb so that the plane of the specimen is 18 cm below the bottom of the bulb. Revolve the turntable and disc at 33 rev/min and expose the specimen to the radiation of the lamp for 24 hours, after which period compare it with the unexposed specimen by visual inspection in bright diffuse daylight. Record the colour of the specimen as stable if no more than a slight change in colour, perceptible with difficulty, is apparent.

APPENDIX B

(*Clause* **4.1**)

SAMPLING

B-l. GENERAL REQUIREMENTS OF SAMPLING

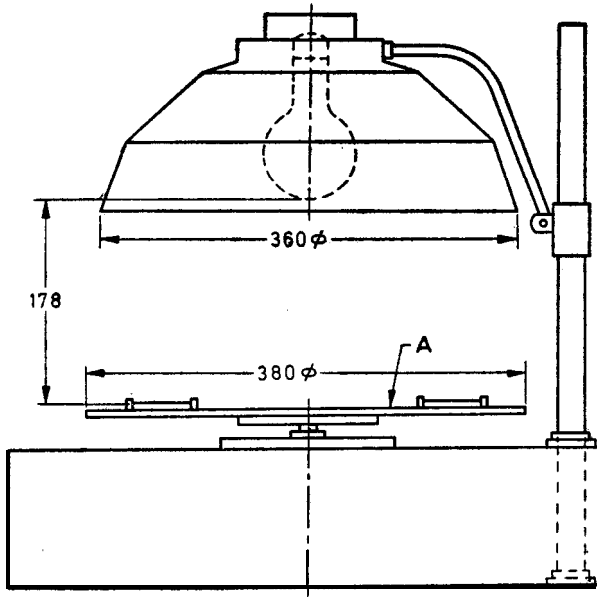
B-1.0 In drawing, preparing, storing and handling test samples, the following precautions and directions shall be observed.

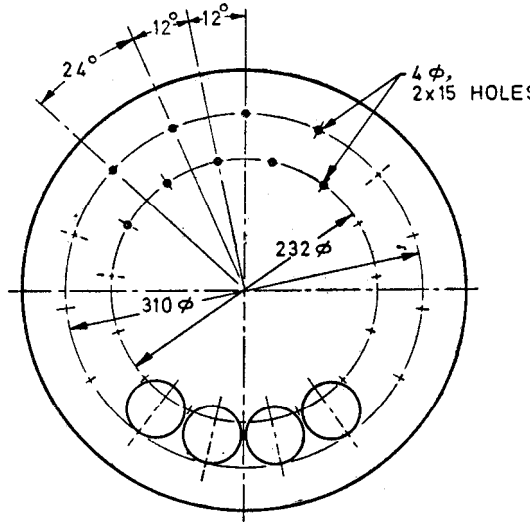
B-l.1 Samples shall not be taken in an exposed place.

B-l.2 The sampling instrument shall be clean and dry.

B-l.3 Precautions shall be taken to protect the samples, the material being sampled, the sampling instrument and the containers for samples from adventitious contamination.

B-1.4 To draw a representative sample, the contents of each container selected for sampling shall be mixed as thoroughly as possible by suitable means.





TO-P PLAN OF A

All dimensions in millimetres,

FIG. 3 COLOUR STABILITY TEST LAMP

B-1.5 The samples shall be placed in clean, dry, air-tight glass or other suitable containers.

B-l.6 The sample containers shall be of such size that they are almost completely filled by the sample.

B-l.7 Each sample container shall be sealed airtight with a suitable stopper after filling, and marked with full details of sampling, the date of sampling and the year of manufacture of the material.

B-2. SCALE OF SAMPLING

B-2.1 Lot — All the containers in a single consignment of the material drawn from a single batch of manufacture shall constitute a lot. If a consignment is declared or known to consist of different batches of manufacture, the containers belonging to the same batch shall be grouped together and each such group shall constitute a separate lot.

B-2.1.1 Samples shall be tested from each lot for ascertaining conformity of the material to the requirements of this specification.

B-2.2 The number of containers (n) to be chosen from the lot shall depend on the size of the lot (N) and shall be as given in Table 2.

TABLE 2 NUMBER OF CONTAINERS TO BE SELECTED FOR SAMPLING

LOT SIZE	NUMBER OF CONTAINERS TO BE SELECTED
(N)	(n)
(1)	(2)
3 to 50	**3**
51 ,, 200	**4**
201 ,, 400	**5**
401 ,, 650	**6**
651 ,, 1 000	**7**
1 001 and above	8

B-2.3 The containers to be selected shall be chosen at random from the lot and in order to ensure the randomness of selection, the random sampling methods given in IS : 4905-1968* may be followed.

*Methods for random sampling.

B-3. TEST SAMPLES AND REFEREE SAMPLE

B-3.1 Preparation of Test Samples

B-3.1.1 *Liquid Component* — Empty the contents of all the sample containers selected into a clean glass-stoppered bottle. Thoroughly mix the contents and divide the composite sample into three equal parts, one for the purchaser, another for the supplier and the third for the referee.

B-3.1.2 *Solid Component* — Empty the contents of all the sample containers selected into a square-sided jar having a capacity of 2 litres and a self-sealing cap. Rotate the jar on its minor axis for two hours at the rate of 25 rev/min. Divide the composite sample into three equal parts, one for the purchaser, another for the supplier and the third for the referee.

B-3.2 Referee Sample — The referee sample shall consist of one composite sample each of the solid component and the liquid component, marked for this purpose and shall bear the seals of the purchaser and the supplier. These shall be kept at a place agreed between the purchaser and the supplier and shall be used in case of dispute.

B-4. NUMBER OF TESTS

B-4.1 Tests for all the characteristics given in 2 shall be conducted on the composite sample.

B-5. CRITERIA FOR CONFORMITY

B-5.1 A lot shall be declared as conforming to this specification if the composite sample satisfies the requirements for each of the characteristics given in 2. If the requirements for any of the characteristics are not met, the lot shall be declared to have not satisfied the requirements of the specification.